

REMARKS

In the Office Action, claim 24 is rejected under 35 U.S.C. §112, first paragraph; claim 6 is rejected under 35 U.S.C. §102; and claims 6 and 23-24 are rejected under 35 U.S.C. §103. Claims 6 and 24 have been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

Claim 24 is rejected under 35 U.S.C. §112, first paragraph. The Patent Office alleges that the subject matter as defined in claim 24 does not satisfy the written description requirement.

Applicants believe that this rejection has been overcome. As previously discussed, claim 24 has been amended to recite, in part, that the lipid source includes a monounsaturated fatty acid and a saturated fatty acid wherein the monounsaturated fatty acid provides at least 50% of energy of the lipid source and wherein the saturated fatty acid provides less than 20% of energy of the lipid source. This is supported in the specification, for example, at page 4, lines 24-30. This amendment was intended for clarification purposes and thus Applicants did not intend this amendment to narrow or disclaim any subject matter in view of same. Accordingly, Applicants respectfully request that the rejection of claim 24 under 35 U.S.C. § 112, first paragraph be withdrawn.

In the Office Action, claim 6 is rejected under 35 USC §102 as allegedly anticipated by U.S. Patent No. 2,893,873 ("Novak 873") or U.S. Patent No. 2,713,349 ("Toulmin 349") or U.S. Patent No. 2,938,799 ("Toulmin 799"). The Patent Office essentially alleges that any one of the cited references discloses each of the features as defined in claim 6. Applicants believe that these rejections should be withdrawn.

As previously discussed, claim 6 has been amended. Claim 6 now recites a method for increasing insulin sensitivity in a mammal including enterally administering a nutritional composition including dextran that has a molecular weight above about 500,000 and that is administered in an amount that ranges from about 2 grams per day to about 15 grams per day. Support for this amendment can be found in the Specification, for example, on page 5 at lines 4-7.

In contrast, Applicants believe that Novak 873 or Toulmin 349 or Toulmin 799 are distinguishable from claim 6. For example, nowhere do any of these references disclose or arguably suggest the amount of dextran that is enterally administered to increase insulin

sensitivity as claimed. The references merely provide a general disclosure regarding dextran as an ingredient in grained confections (see, Novak 873), as an ingredient in an ice cream, ices or the like (see, Toulmin 349) or as an ingredient in a pudding composition (see, Toulmin 799). Indeed, both Toulmin 349 and Toulmin 799 emphasize the use of a low molecular weight dextran including as low as 5,000 in further contrast to the claimed dextran that has a molecular weight above about 500,000. See, Toulmin 799, col. 2, lines 54-59; and Toulmin 349, col. 2, lines 43-46.

Based on at least these reasons, Applicants believe that the cited art is deficient with respect to the claimed invention. Therefore, Applicants respectfully submit that Novak 873 or Toulmin 349 or Toulmin 799 fail to disclose, either explicitly or inherently, the claimed invention as defined by claimed 6.

Accordingly, Applicants respectfully submit that the anticipation rejection of claim 6 be withdrawn.

In the Office Action, Claims 6 and 23-24 are rejected under 35 USC §103 as allegedly unpatentable over European Patent Document No. 0382355 (Mitsubishi) in view of Novak 873, Toulmin 349 or Toulmin 799. The Patent Office primarily relies on Mitsubishi and thus further relies on Novak 873 or Toulmin 349 or Toulmin 799 in support of the obviousness rejection.

Applicants believe that the obviousness rejection has been overcome. As previously discussed, the claimed invention relates to methods of increasing insulin sensitivity by administering a nutritional composition that includes dextran in specified amounts. More specifically, the dextran has a molecular weight above about 500,000 and that is enterally administered in an amount that ranges from about 2g per day to about 15g per day as required by the claimed invention. The present invention provides a convenient and simple way of selectively increasing the production of proprionate in the gastrointestinal tract and thus increasing insulin sensitivity by the enteral administration of dextran as claimed.

In contrast, the Mitsubishi reference is clearly deficient with respect to the claimed invention. For example, Mitsubishi teaches that low molecular dextran allegedly promotes the growth of *Bifidobacteria* in the intestine, yet even fails to provide convincing data for demonstrating such an enhanced growth. Indeed, the cell counts were 9.9 ± 0.4 and 10.2 ± 0.4 before and after dextran administration, respectively, as disclosed in Table 1. In addition,

Mitsuhashi merely suggests that low molecular dextran might have an effect with respect to the prevention of geriatric diseases, such as hypertension, diabetes, myocardial infarction and malignant tumors. See, Mitsuhashi, p.5, lines 39-43. This is purportedly due to a synthesis of vitamins or a decrease in the intestinal pH level as further disclosed in Mitsuhashi at p.2, lines 12-20. Thus, the increase of insulin sensitivity cannot be derived from Mitsuhashi as it should be clear Mitsuhashi that a prevention of diabetes may be obtained by various other effects, such as by weight reduction, as well as by vitamins or a decreased intestinal pH level as provided in Mitsuhashi and discussed above. Id.

Moreover, Mitsuhashi is specifically directed to *Bifidobacteria*, which bacteria according to Mitsuhashi produce organic acids, such as acetic acid and lactic acid, thus resulting in a decrease of the intestinal pH. See, Mitsuhashi, p. 2, lines 12-13. Nowhere does Mitsuhashi relate to the production of propionic acid, let alone increasing amounts thereof. Thus, clearly Mitsuhashi fails to disclose or suggest that an enteral administration of dextran in specified amounts as claimed can result in an increased amount of propionic acid in the gastro-intestinal tract and, thus in a direct consequence therefrom, in an increased insulin sensitivity as required by the claimed invention.

Indeed, Mitsuhashi effectively teaches away from an administration of dextran as Mitsuhashi provides that the administration of dextran correlates to an increased production of acetate (See, Mitsuhashi, p. 2, lines 12-13), thus resulting in increased plasma fatty acid concentrations (See, Specification, p. 1, lines 26-27) at levels that should be considered as detrimental for any person and in particular for persons in need of food supplements for increasing insulin sensitivity. Therefore, on its own, Mitsuhashi is clearly distinguishable from the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on Novak 873 or Toulmin 379 or Toulmin 799, even if combinable, to remedy the deficiencies of Mitsuhashi. These references fail to provide little, if any, additional support to the Mitsuhashi reference. Indeed, the Patent Office has not clearly discussed how these references can add to and supplement what Mitsuhashi allegedly discloses. Moreover, what additional support these references may arguably provide is still insufficient in scope to remedy the deficiencies of Mitsuhashi. As previously discussed, these references merely provide a general disclose relating

to the administration of dextran and thus are deficient with respect to the specific type and amount of dextran that is enterally administered to increase insulin sensitivity as required by the claimed invention. Therefore, even if combinable, one skilled in the art would not be inclined to modify Mitsuhashi to arrive at the claimed invention in view of same.

Based on at least these reasons, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants respectfully submit that the cited art even if combinable fails to render obvious the claimed invention.


Accordingly, Applicants respectfully request the obviousness rejection be withdrawn.

Applicants again note for the record that the Patent Office has not provided the Examiner's initials with respect to the reference entitled "Dietary Fructans, Roberfroid et al., Annu. Rev. Nutr., 1998, Vol. 18, pages 117-143 as referenced in PTO Form 1449 previously submitted by Applicants. Applicants believe that this reference was also submitted to the Patent Office at that time. Indeed, the Patent Office has not indicated otherwise. Therefore, Applicants respectfully once again request that this reference be officially made of record and that the Patent Office provide Applicants with a copy of PTO Form 1449 with the Examiner's initials indicating same. However, if by chance, the Patent Office does not have a copy of this reference, Applicants respectfully request that the undersigned attorney of record be contacted directly such that a copy of same can be forwarded to the Patent Office.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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